Application No.: 10/544,212 Docket No.: 17563/004001

REMARKS

Please reconsider the application in view of the above amendments and the following remarks. Applicant thanks the Examiner for carefully considering this application.

Disposition of Claims

Claims 1-12 were pending in this application. Claim 13-20 have been added by this reply. Therefore, claims 1-20 are pending after the amendments. Claims 1 and 14 are independent. The remaining claims depend, directly or indirectly, from claim 1 or claim 14.

Claim Amendments

Claims 1-12 have been amended to clarify the invention recited. New claims 13-20 are added, which include an isolation step after the protease reaction. Support for this limitation can be found at least in Example 1. No new matter is introduced.

Rejection(s) under 35 U.S.C. § 103

Claims 1-12

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inazu, et al. (in IDS, Peptide Science 1998, M. Kondo Edition, pp. 153-156) (hereinafter "Inazu") in view of Koketsu, et al. (The Journal of Food Science, 1993, Vol. 58, No. 4, pp. 743-747) (hereinafter "Koketsu") and further in view of Yamamoto, K. (Journal of Bioscience and Bioengineering, 2001, Vol. 92, No. 6, pp. 493-501) (hereinafter "Yamamoto"), and further in view of Narahashi, et al. (Journal of Biochemistry, 1967, Vol. 62, No. 6, Abstract) (hereinafter "Narahashi"). Claim 1 has been amended. To the extent that this rejection may still apply to the amended claims, this rejection is respectfully traversed.

The present invention relates to methods for preparing asparagine-linked oligosaccharide derivatives by subjecting delipidated egg yolk to a protease, followed by treatment with a peptidase. The Asn-linked oligosaccharides thus obtained are then derivatized with a lipophilic protecting group and then purified on a reverse-phase column.

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Specifically, a method as recited in claim 1 includes, *inter alia*, the steps of "(a) treating a delipidated egg yolk with orientase to obtain a mixture of peptide-linked oligosaccharides; (b) treating the mixture of peptide-linked oligosaccharides with actinase to obtain a mixture of asparagine-linked oligosaccharides."

In contrast, Inazu discloses that high-mannose type oligosaccharide may be obtained by treating ovalbumin with pronase. Koketsu discloses a method of preparing oligosaccharides by chemical hydrolysis of delipidated egg yolk (DEY) with hydrazine at high temperature. Applicant respectfully submits that there is no teaching, suggestion, or motivation for one skilled in the art to combine Inazu and Koketsu to arrive at the claimed invention because Inazu and Koketsu use different starting materials and very different processes (enzymatic versus chemical process).

Even if Inazu and Koketsu were properly combinable, a combination of Inazu and Koketsu will not produce a method of the invention. A method of the invention, as recited in the amended claim 1, uses a two-step enzymatic process – first with a protease (proteinase) and then with a peptidase. Specifically, the amended claim 1 recites a method that uses orientase as the protease and actinase as the peptidase. Inazu fails to teach a two-step enzymatic process, let alone the two specific enzymes, orientase and actinase. Koketsu does not teach that which is missing in Inazu.

As shown in the attached Declaration under 37 C.F.R. § 1.132, different enzymes produce different products even when they are used in similar procedures. For example, when orientase and actinase are replaced with pronase and pronase (i.e., pronase is used in both enzymatic steps), the resultant product composition is different from that produced with orientase and actinase (*see* HPLC profiles (A) and (C) in the attached Declaration). The different product profiles attests to the importance of the enzymes used.

Because Inazu fails to teach at least one limitation of the amended claim 1, i.e., "(a) treating a delipidated egg yolk with orientase to obtain a mixture of peptide-linked oligosaccharides; (b) treating the mixture of peptide-linked oligosaccharides with actinase to obtain a mixture of asparagine-linked oligosaccharides," and Koketsu, Yamamoto, and

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Narahashi fail to teach that which is missing in Inazu, the amended claim 1 is patentable over Inazu in view of Koketsu, and further in view of Yamamoto, and further in view of Narahashi. Dependent claims 2-12 should also be patentable for at least the same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

New claims

Claim 13 depends from claim 1. Therefore, new claim 13 should also be patentable for at least the same reasons discussed above.

Claim 14 recites a method that uses a protease and a peptidase in a two-step process. In addition, the claim recites an isolation step, in which the initial peptide-linked oligosaccharide products are isolated before peptidase treatment.

In contrast, Inazu teaches a process using pronase as both a protease and a peptidase. Inazu doe not teach or suggest isolation of the peptide-linked oligosaccharide products. Koketsu, Yamamoto, and Narahashi also fail to teach or suggest that which is missing in Inazu. Therefore, claim 14 is patentable over Inazu in view of Koketsu, further in view of Yamamoto, and further in view of Narahashi. Dependent claims 15-20 should also be patentable for at least the same reasons.

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Conclusion

Applicant believes this reply is fully responsive to all outstanding issues and places this application in condition for allowance. If this belief is incorrect, or other issues arise, the Examiner is encouraged to contact the undersigned or his associates at the telephone number listed below. Please apply any charges not covered, or any credits, to Deposit Account 50-0591 (Reference Number 17563/004001).

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Respectfully submitted,

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Attachments

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